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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,152	06/20/2003	Sharon A. Baughman	P1775R1D1	5622

9157 7590 05/11/2006

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EXAMINER	
HOLLERAN, ANNE L	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 05/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,152	BAUGHMAN ET AL.	
	Examiner	Art Unit	
	Anne L. Holleran	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-105 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-105 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 30 and 98, drawn to methods for treatment of cancer or of disorders characterized by overexpression of ErbB2 receptor comprising administering an initial dose of an anti-ErbB2 antibody of at least approximately 5mg/kg and administering a plurality of subsequent doses that are the same or less than the initial dose; and drawn to methods further comprising administering a chemotherapeutic agent listed on pages 14-15 of the specification, classified in class 424, subclass 130.1.

II. Claims 31, 32 and 99, drawn to methods for treatment of cancer or of disorders characterized by overexpression of ErbB2 receptor comprising administering an initial dose of an anti-ErbB2 antibody of at least approximately 5mg/kg and administering a plurality of subsequent doses that are the same or less than the initial dose; and drawn to methods further comprising administering a taxoid, classified in class 424, subclass 130.1.

III. Claims 34-36, drawn to methods for treatment of cancer or of disorders characterized by overexpression of ErbB2 receptor comprising administering an initial dose of an anti-ErbB2 antibody of at least approximately 5mg/kg and administering a plurality of subsequent doses that are the same or less than the

initial dose; and drawn to methods further comprising administering an anthracycline, classified in class 424, subclass 130.1.

IV. Claims 102 and 104 (to the extent claims read on methods comprising administering an anti-EGFR antibody), drawn to drawn to methods for treatment of cancer comprising administering an initial dose of an anti-EGFR antibody of at least approximately 5mg/kg and.administering a plurality of subsequent doses that are the same or less than the initial dose, classified in class 424, subclass 130.1.

V. Claims 102 and 104(to the extent claims read on methods comprising administering an anti-ErbB3 antibody), drawn to methods for treatment of cancer comprising administering an initial dose of an anti-ErbB3 antibody of at least approximately 5mg/kg and administering a plurality of subsequent doses that are the same or less than the initial dose, classified in class 424, subclass 130.1.

VI. Claims 102 and 104(to the extent claims read on methods comprising administering an anti-ErbB4 antibody), drawn to methods for treatment of cancer comprising administering an initial dose of an anti-ErbB4 antibody of at least approximately 5mg/kg and administering a plurality of subsequent doses that are the same or less than the initial dose,, classified in class 424, subclass 130.1.

VII. Claims 38-85, 100 and 105, drawn to articles of manufacture comprising an ErbB2 antibody or an anti-ErbB antibody, classified in class 530, subclass 388.1.

2. Claims 1-29, 33,37, 86-97, 101 and 103(to the extent 101 and 103 read on treatment of cancer comprising administering an ErbB2 antibody) link inventions I-III. Claims 101 and 103

MLH 8/21/06 ~~101 and 103~~ (to the extent 101 and 103 read on treatment of cancer comprising administering an ErbB antibody that is not an anti-ErbB2 antibody) link inventions IV-VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicant is advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims in the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. The inventions are distinct, each from the other, for the following reasons:

The methods of Inventions I-VI differ in the population of patients to be treated and in the reagents used. Inventions I-III recite a method for treating a disorder characterized by overexpression of ErbB2 or for treatment of cancer, comprising the use of an anti-ErbB2 antibody, whereas Invention IV comprises the use of an anti-EGFR antibody; Invention V comprises the use of an anti-ErbB3 antibody; and Invention VI comprises the use of an anti-ErbB4 antibody. ErbB2, EGFR, ErbB3 and ErbB4 are each separate and distinct protein products. Therefore, the antibodies that bind to these proteins are separate and distinct products.

Furthermore, disorders or cancers that may overexpress each of these separate and distinct products may be different. Within Invention groups I-III, Invention I recites the use of a combination of ErbB2 and a chemotherapeutic agent (restricted to those listed on pages 14-15); Invention II recites the use of a combination of ErbB2 and a taxoid; Invention III recites the use of a combination of ErbB2 and an antracycline. The chemotherapeutic agents listed on page 14-15, taxoids and anthracyclines are each separate and distinct chemotherapeutic agents, each having its own unique structure. These chemotherapeutic agents encompass agents that are useful in the treatment of many different diseases. Thus Inventions I-VI are patentable distinct.

Inventions VII and any one of I-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the products of Invention VII, which encompasses at least four different and distinct antibody products, can be used in a method for purifying the antigen that binds to the antibody, which is a method that is a materially different process of using the products of Invention VII than any of the in vivo methods of treatment of Inventions I-VI.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Furthermore, it would be an undue burden to

examine the separate inventions together, because it would require searching for at least four separate methods of using four distinct antibodies.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Election of Species Requirement:

A) If Invention I is elected, then the following election of species is required:

6. Claims 1-21, 27, 28, 30, 33, 37-37 and 86-98 are generic to the following disclosed patentably distinct species: **chemotherapeutic agent listed on pages 14-15**. The species are independent or distinct because each chemotherapeutic agent is a distinct chemical compound. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

B) If Invention VII is elected, then the following election of species is required:

7. Claim 105 is generic to the following disclosed patentably distinct species:

a) anti-Erb2 antibody

b) anti-EGFR antibody

c) anti-ErbB3 antibody

d) anti-ErbB4 antibody

The species are independent or distinct because each antibody binds to a distinct protein product, each having its own distinct structure. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an

allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the

status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
May 2, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER